

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION**

LOUISIANA HEALTH SERVICE &
INDEMNITY COMPANY D/B/A/ BLUE
CROSS AND BLUE SHIELD OF
LOUISIANA, and HMO LOUISIANA,
INC., on behalf of themselves and all others
similarly situated,

Plaintiffs,

v.

JANSSEN BIOTECH, INC., JANSSEN
ONCOLOGY, INC., JANSSEN
RESEARCH & DEVELOPMENT, LLC,
and BTG INTERNATIONAL LIMITED,

Defendants.

Case No. 1:19-cv-00474-LMB-JFA

**DECLARATION OF JEROME A. SWINDELL IN SUPPORT OF DEFENDANTS’
JOINT MOTION TO TRANSFER VENUE PURSUANT TO 28 U.S.C. § 1404(a)**

I, Jerome A. Swindell, declare and state as follows:

1. I am Chief Antitrust Counsel for Johnson & Johnson (“J&J”) and have held this position since February 2018. Prior to my current position, I have been employed by J&J since March 2005 in various legal roles.
2. I am authorized to make the statements in this Declaration, which are true of my personal knowledge, or upon information and belief, including inquiry of relevant J&J employees.
3. J&J is incorporated under the laws of the State of New Jersey with its principal place of business at One Johnson & Johnson Plaza in New Brunswick, New Jersey.

4. Janssen Biotech, Inc. is a wholly owned subsidiary of J&J, incorporated under the laws of the Commonwealth of Pennsylvania with its principal place of business in Horsham, Pennsylvania. Janssen Biotech transacts business in the State of New Jersey and maintains a significant corporate and operational presence in Titusville, New Jersey.

5. Janssen Oncology, Inc. is a wholly owned subsidiary of J&J, incorporated under the laws of the State of Delaware, with its principal place of business in Los Angeles, California. Janssen Oncology transacts business in the State of New Jersey and maintains a significant corporate and operational presence in both Titusville, New Jersey and Horsham, Pennsylvania.

6. Janssen Research & Development, LLC is a wholly owned subsidiary of J&J, organized under the laws of the State of New Jersey, with its principal place of business in Raritan, New Jersey.

7. I have reviewed the Complaint filed by Louisiana Health Service & Indemnity Company D/B/A/ Blue Cross and Blue Shield of Louisiana, and HMO Louisiana, Inc. on behalf of themselves and all others similarly situated (collectively, “Plaintiffs”).

8. Zytiga® (abiraterone acetate) is an anti-cancer drug for the treatment of metastatic castration-resistant prostate cancer.

9. On September 2, 2014, the United States Patent and Trademark Office (“USPTO”) issued U.S. Patent No. 8,822,438 (“the ’438 Patent”) for “[a] method for the treatment of a prostate cancer in a human comprising administering to said human a therapeutically effective amount of abiraterone acetate or a pharmaceutically acceptable salt thereof and a therapeutically effective amount of prednisone,” which lists Janssen Oncology, Inc. as the assignee.

10. On July 31, 2015, Janssen Biotech, Inc., Janssen Oncology, Inc., and Janssen Research & Development, LLC (collectively “Janssen”), together with BTG International Ltd., instituted a patent infringement action in the United States District Court for the District of New Jersey pursuant to the Hatch-Waxman Act for infringement of the ’438 Patent. *See* Complaint, *BTG Int’l, Ltd. et al. v. Amneal Pharm. LLC, et al.*, No. 2:15-cv-05909-KM-JBC (D.N.J. July 31, 2015), ECF No. 1.

11. The patent infringement litigation was overseen and directed by J&J legal staff located in New Brunswick, New Jersey.

12. Beginning in December 2015 and through 2017, at least five generic pharmaceutical companies filed petitions at the USPTO for *inter partes* review (“IPR”) of the ’438 Patent by the Patent Trial and Appeal Board (“PTAB”), which consolidated them into three IPRs and subsequently held the challenged claims unpatentable.

13. On October 26, 2018, following a bench trial, District Court Judge Kevin McNulty issued a written decision in the patent infringement lawsuit. Judge McNulty issued an amended version of that decision on October 31, 2018. Attached hereto as Exhibit A is a true and accurate copy of Judge McNulty’s October 31, 2018 amended opinion. *See* Ex. A, *BTG Int’l, Ltd. et al. v. Amneal Pharm. LLC, et al.*, No. 2:15-cv-05909-KM-JBC (D.N.J. Oct. 31, 2018).

14. Judge McNulty’s decision was consolidated with those of the PTAB for purposes of appeal before the United States Court of Appeals for the Federal Circuit. *See* *BTG Int’l, Ltd. et al. v. Amneal Pharm. LLC, et al.*, No. 2019-1147 (Fed. Cir. 2018). On May 14, 2019, the Federal Circuit affirmed the PTAB’s decision as to one of the IPRs (Wockhardt) and dismissed as moot the remaining two IPRs (Amerigen and Mylan) and the district court appeal. Attached hereto as

Exhibit B is a true and accurate copy of the Federal Circuit's opinion. *See* Ex. B, *BTG Int'l Ltd. v. Amneal Pharm. LLC*, No. 19-1147, 2019 WL 2094302 (Fed. Cir. May 14, 2019).

15. There is also a False Claims Act litigation pending against J&J and Janssen. That lawsuit raises allegations of fraud on the USPTO that purportedly led to the issuance of the '438 Patent, which caused J&J and Janssen to submit allegedly false claims to the U.S. Government for the payment and/or reimbursement of Zytiga. *See* First Am. Compl., *United States of America et al. v. Janssen Biotech, Inc. et al.*, No: 2:19-cv-12107-KM-JBC (D.N.J. Oct. 23, 2018), ECF No. 7.

16. The False Claims Act lawsuit was initially filed in the United States District Court for the Northern District of California before being transferred to the District of New Jersey on April 29, 2019. Attached hereto as Exhibit C is a true and accurate copy of the district court's order granting J&J and Janssen's motion to transfer venue. *See* Ex. C, Order Granting Motion To Transfer Venue, *United States of America et al. v. Janssen Biotech, Inc. et al.*, No: 2:19-cv-12107-KM-JBC (D.N.J. April 29, 2019), ECF No. 51.

17. Subsequently, on May 6, 2019, the District of New Jersey assigned the False Claims Act litigation to Judge McNulty.

18. Zytiga is part of Janssen's pharmaceutical product portfolio. The vast majority of Janssen's pharmaceutical business is based out of Janssen operations located in New Jersey and nearby in Pennsylvania.

19. For instance, Janssen Research & Development oversees the formulation and development of Zytiga through a multifunctional compound development team primarily based out of Raritan, New Jersey.

20. The core compound development team is composed of approximately twelve individuals who represent a variety of operating functions. For Zytiga, the compound development team leader sits in Raritan, New Jersey and is charged with overseeing the product's development and representing the product before internal governance committees. Recent and potentially relevant compound development team leaders include: (i) Michael Meyers, no longer with the Company and, upon information and belief, located in the greater New York City area; (ii) Bob Charnas, no longer with the Company and located in the greater New York City area; and (iii) Michael Smith, presently located in Raritan, New Jersey. Compound development team leaders are knowledgeable about Zytiga's path to development, and could speak to pre-launch product strategy, such as financing and planned marketing, and post-launch market expansion.

21. Other functions represented by the core compound development team include clinical pharmacy, global regulatory affairs, translational medicine and research, strategic marketing, global medical affairs, and global market access. Like much of Janssen's pharmaceutical business, these functions operate out of New Jersey and Pennsylvania. Additional functions represented on the core compound development team include pharmaceutical development and manufacturing services and clinical and research. Neither of these functions operate in or near Virginia.

22. Strategic marketing's role on the compound development team is to assess the value proposition of relevant patient populations and lead decisions over when and whether to enter those patient populations. Strategic marketing for research and development is also located in Raritan, New Jersey. Geraldine Shank from strategic marketing has been assigned to Zytiga since 2017. Prior to Ms. Shank, the following individuals held this role: Rocio Bueno (2016); Sheelu Samuel (2015); Gataen Leblay (2014); and Paul Short (2013). Upon information and

belief, most of these individuals reside in New Jersey, New York, or Pennsylvania. These individuals could speak to market evaluation and market-entry strategies for Zytiga.

23. The core compound development team was also supported by various other functions, such as legal, finance, and communications.

24. The J&J legal team that prosecuted the '438 Patent was located in New Brunswick, New Jersey and included Andrea Kamage and Timothy Tracy.

25. Andrea Kamage is currently Assistant Patent Counsel at J&J, located in La Jolla, California. From 2011 until August 14, 2013, including at the time of the June 4, 2013 prosecution submissions identified by Plaintiffs' Complaint, Ms. Kamage was Senior Patent Counsel at J&J and located in New Brunswick, New Jersey.

26. Timothy Tracy is currently Assistant General Counsel, Patents at J&J, located in New Brunswick, New Jersey. Mr. Tracy has been located in New Brunswick, New Jersey throughout his employment in J&J's law department, beginning in 2000 and including at the time of the June 4, 2013 prosecution submissions identified by Plaintiffs' Complaint.

27. The application for the '438 Patent, as well as supporting material, was filed from J&J's New Jersey office(s) to the USPTO.

28. Janssen R&D's finance operations are located in New Jersey.

29. Kellie McLaughlin supported Zytiga from a communications perspective. She continues to be employed by Janssen at a research and development site in Springhouse, Pennsylvania, approximately 30 miles from the New Jersey border. Ms. McLaughlin's group frequently shifts between Springtown, Pennsylvania and Raritan, New Jersey. Ms. McLaughlin could speak to

the communication strategy for promoting and marketing Zytiga to the public and across various patient populations.

30. Following FDA-approval of Zytiga, much of the product support transitioned to Janssen's commercial business. Like research and development, commercial support for Zytiga is provided by various J&J and Janssen commercial groups that are located primarily in New Jersey and neighboring Horsham, Pennsylvania, approximately 30 miles from the New Jersey border.

31. Much of the Janssen pharmaceutical business operates on an "open office space" basis between Janssen's Horsham, Pennsylvania, and Titusville, New Jersey locations. Janssen has designated space for many of the Horsham campus's business units, and Janssen personnel employed in those units frequently travel between and work from the Titusville campus.

32. Commercial marketing and sales for Zytiga is supported by two groups that work collaboratively at the leadership level to align on strategic decision-making: Janssen Biotech, Inc. and J&J's Strategic Customer Group. Both groups report to Scott White, Company Group Chairman, North America, Janssen Pharmaceutical Companies. Mr. White is primarily located in Titusville, New Jersey.

33. The marketing group at Janssen is overseen by Reshema Kemps-Polanco, Vice-President, Sales & Marketing, Solid Tumor. Ms. Kemps-Polanco is supported by Melissa Magee, Director of Marketing, and Cynthia Jones, Group Product Director for Zytiga. They are responsible for marketing Zytiga to individual prescribers, such as physicians or oncologists, and are familiar with Janssen marketing strategies to those prescribers, which includes Zytiga's efficacy and success in treating prostate cancer. They would be capable of speaking to such strategies. The marketing department for Janssen's Solid Tumor group, including the three individuals listed in this paragraph, operate out of Janssen's Horsham and Titusville locations.

34. Louis Langas was previously the Group Product Director in charge of marketing for Zytiga. He was responsible for the pre-launch strategy for Zytiga, including the strategic planning for Zytiga marketing and sales. Mr. Langas could speak to the marketing and commercial strategy for Zytiga, as well as to Zytiga's post-launch commercial success. Mr. Langas currently resides in New Jersey.

35. J&J's pharmaceutical Strategic Customer Group ("SCG"), led by Blazine Penkowski, is a broader strategic account management team that markets Zytiga to payer-entities, such as managed care organizations ("MCOs") or physician group purchasing organizations ("GPOs"). SCG reports to a separate entity J&J Heath Care Systems Inc. ("JJHCS") located in Piscataway, New Jersey. Kevin Hamill, Vice President of Strategic Accounts, reports to Ms. Penkowski. Both have their primary office locations in Titusville, New Jersey. Both are knowledgeable, and could speak to, marketing strategies aimed at MCOs and GPOs.

36. Both of these marketing and sales groups work closely with Dimitry Gitarts from Janssen's strategic pricing group. Mr. Gitarts, an employee of JJHCS, collaborates with Janssen's commercial sales and marketing teams to evaluate strategic pricing in the context of market share. Mr. Gitarts further sets pricing strategy through the assessment and calculation of discounts to MCOs and GPOs. As part of his responsibilities, Mr. Gitarts monitors market conditions, including any potential generic entry. Mr. Gitarts, in consultation with Janssen Biotech, Inc., sets the overall pricing strategy for Zytiga, and could speak to how Janssen evaluates Zytiga's price in response to market conditions. Mr. Gitarts and his colleagues are located primarily in Titusville, New Jersey.

37. Janssen does maintain regional field sales representatives all over the country to personally manage individual payer accounts. However, regional field sales staff are not

responsible for setting sales strategy or policy; nor does regional field sales staff carry any decision-making authority with respect to sales policy or strategy for Zytiga, including product pricing. Rather, regional field sales staff take all of their direction from, and execute the sales and pricing strategy set by, Mr. Gitarts and other sales and marketing leadership, all of whom are located in the Titusville, New Jersey or Horsham, Pennsylvania area. Regional field sales staff also have no role in patent prosecution or enforcement.

38. JJHCS, located in Piscataway, New Jersey, is responsible for contracting with its managed care clients, including HMOs like Plaintiffs here. JJHCS personnel take their direction from Mr. Gitarts and are tasked with drafting and executing the contracts that reflect that strategy. At JJHCS, Bill Condon oversees contacts with managed care clients that cover Zytiga and is knowledgeable about contracting strategies with those managed care customers. JJHCS also manages contracts for GPOs. Janis Goldfeder and Cristina McCabe, both located in Piscataway, oversee those contracts and could speak to Zytiga contracting strategies with those purchasers.

39. Janssen utilizes a shared finance center that assigns individuals within the finance department to support specific Janssen therapeutic areas. Janssen's commercial finance arm is located in Titusville, New Jersey and Horsham, Pennsylvania. Finance support for oncology is led by Salvatore Giovine, Senior Finance Director for Oncology; he works out of the New Jersey and Pennsylvania area. Shelly Shadle, Finance Controller Pricing & Strategy, SCG, who works out of the Horsham and Titusville campuses, is responsible for gross and net calculations for the portfolio of Janssen products including Zytiga. Michelle Small is a Finance Manager for Janssen, located in Horsham, Pennsylvania, and previously had responsibility for preparing and maintaining the financial statements for Zytiga. Ms. Small is knowledgeable about, and could

speak to, the revenues, costs, and expenses associated with the Zytiga product. All three could explain the financial impact of changes to Zytiga's market price.

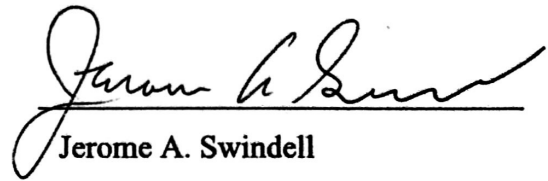
40. Regulatory staff responsible for Janssen's pharmaceutical business is also primarily located in Titusville, New Jersey. Le Chung is the Regulatory Liaison for Janssen and the regulatory affairs point of contact for interactions with the U.S. Food & Drug Administration ("FDA"). She is responsible for FDA interactions as to Zytiga and could speak to Zytiga's FDA approval process. Ms. Chung is located in Titusville, New Jersey.

41. Individuals who are knowledgeable about Zytiga and the facts or allegations set forth in Plaintiffs' Complaint are all located outside of the Eastern District of Virginia. The significant majority of these individuals are located in or near New Jersey. Accordingly, individuals that are most likely, at this early stage of proceeding, to be potential fact witnesses are by and large located in or near New Jersey.

42. Similarly, documents that may potentially be relevant in this action, such as those relating to commercial strategy, marketing, sales, and finance, are also more likely to be located in or near New Jersey given both the location of individuals knowledgeable about Zytiga as well as the locus of Janssen's pharmaceutical and small molecule business.

43. It would be considerably more convenient, less burdensome, and less expensive for the Janssen entities and for the Janssen employees who may potentially be called to testify in this action, should it proceed to trial, if this action were transferred to the District of New Jersey.

I declare under penalty of perjury that the foregoing is true and correct. Executed on 23rd day of May, 2019 at New Brunswick, New Jersey.



Jerome A. Swindell